UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION **This Document Relates to All Actions**	MDL No. 2875 Honorable Robert B. Kugler, District Court Judge Oral Argument Requested

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS' MOTION TO EXCLUDE THE OPINIONS OF LAURA PLUNKETT, PH.D.

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INTRODUCTION

Dr. Laura M. Plunkett, a career litigation expert, seeks to come to court as a cheerleader for plaintiffs' case, parroting other experts and deflect any questions that would require actual expertise on her part. Dr. Plunkett's opinions fail to satisfy the requirements of Rule 702 and *Daubert* for a host of reasons.

First, Dr. Plunkett is not qualified to offer most of her science-based opinions, and presumably for this reason, mostly regurgitates the opinions of plaintiffs' expert chemist Dr. Stephen Hecht on the relevant science. To the extent Dr. Plunkett does offer any original science-based opinions, she opines that ***any*** level of nitrosamine exposure increases the risk of cancer, which is the sort of improper and inadmissible "any exposure" theory that has been rejected by one court after another.

Second, Dr. Plunkett seeks to provide an overview of the legal and regulatory requirements at issue in this case and to tell the jury that ZHP failed to comply with those requirements. But Dr. Plunkett mostly parrots the regulatory opinions of another plaintiffs' expert, Susan Bain (who is herself grossly unqualified). Additionally, Dr. Plunkett's legal opinions regarding bioequivalence, adulteration, and what the FDA "requires" impermissibly usurp the role of the Court and the jury, as this Court has recognized with respect to another plaintiffs' expert. (*See* Ops. on Certification of Proposed Classes under FRCP Rule 23 and

on Class Certification Expert Reports under FRE 702 ("Class Certification Ruling") at 91, ECF No. 2261 (excluding expert Dr. Ramin Najafi's opinions "about what is bioequivalence" because it "wades too far into the factfinder's domain").)

For all of these reasons, the Court should exclude Dr. Plunkett's testimony.

BACKGROUND

Dr. Plunkett's expert report purports to address: (1) "the human health risks associated with the presence of contaminants and impurities in a drug such as valsartan that is taken on a repeated basis by patients to treat chronic health conditions"; and (2) "the regulations and industry standards that apply with respect to manufacturing of human drug products." (Report of Laura M. Plunkett ("Plunkett Rep.") at 7, Oct. 31, 2022 (Ex. 1 to the Certification of Jessica Davidson ("Davidson Cert.")).)

Nowhere in her report, however, does Dr. Plunkett lay out the risk assessment she claims she will perform, and it appears that this part of her introduction is simply boilerplate, copied from one of her many other expert reports in other litigation. Dr. Plunkett does offer other science-based and regulatory-based opinions, but those opinions should be excluded for the reasons set forth below.

ARGUMENT

The proponent of expert testimony bears the burden of establishing the admissibility of expert testimony by a preponderance of the evidence. *See In re TMI Litig.*, 193 F.3d 613, 663 (3d Cir. 1999), *amended by* 199 F.3d 158 (3d Cir. 2000).

Under Federal Rule of Evidence 702, expert testimony is only admissible where the witness is qualified to render expert testimony and the testimony offered "both rests on a reliable foundation and is relevant to the task at hand." *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 597 (1993); Fed. R. Evid. 702 (expert testimony is admissible only if the witness is qualified "by knowledge, skill, experience, training, or education" and the opinion is both "based on sufficient facts or data" and "the product of reliable principles and methods" that have been "reliably applied . . . to the facts of the case"); *see also Ruggiero v. Yamaha Motor Corp., U.S.A.*, 778 F. App'x 88, 93 (3d Cir. 2019) ("Rule 702 embodies a trilogy of restrictions on expert testimony: qualification, reliability and fit.") (citation omitted); *In re Paulsboro Derailment Cases*, 746 F. App'x 94, 98 (3d Cir. 2018) ("A district court, in exercising its gatekeeping function, 'must ensure that any and all scientific testimony or evidence admitted is not only relevant, but reliable.'") (quoting *Daubert*, 509 U.S. at 589). In determining whether expert testimony is reliable, a court must assess "whether the reasoning or methodology underlying the testimony is

scientifically valid and . . . whether that reasoning or methodology properly can be applied to the facts in issue." *Daubert*, 509 U.S. at 592-93.

The U.S. Court of Appeals for the Third Circuit has explained that "any step" in an expert's reasoning "that renders the analysis unreliable under the *Daubert* factors renders the expert's testimony inadmissible." *In re Zoloft (Sertraline Hydrochloride) Prods. Liab. Litig.*, 858 F.3d 787, 797 (3d Cir. 2017); *see also, e.g.*, *Perry v. Novartis Pharms. Corp.*, 564 F. Supp. 2d 452, 459 (E.D. Pa. 2008) (explaining that this principle holds regardless of "whether the step completely changes a reliable methodology or merely misapplies that methodology") (citation omitted). In addition, if the assumptions underlying an expert's ultimate conclusion are shown to be inadmissible, then the entire opinion must be excluded. *See, e.g.*, *Coffey v. Dowley Mfg., Inc.*, 187 F. Supp. 2d 958, 976 (M.D. Tenn. 2002) ("Like a house of cards, once those foundations are disproved, the whole analysis collapses. Here, [the expert's] use and reliance upon a faulty finite element analysis constituted a faulty method, based upon faulty principles."), *aff'd*, 89 F. App'x 927 (6th Cir. 2003). It is also axiomatic that a court need not "admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert." *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997); *see also Bowers v. Nat'l Collegiate Athletic Ass'n*, 564 F. Supp. 2d 322, 350 (D.N.J. 2008) (excluding expert opinion where expert's "throwaway observation . . . appear[ed] to be based on little more than

'subjective belief or unsupported speculation'") (citation omitted); *Grimes v. Hoffmann-LaRoche, Inc.*, 907 F. Supp. 33, 38 (D.N.H. 1995) ("[A]n expert cannot establish that a fact is generally accepted merely by saying so.").

Dr. Plunkett's proposed testimony fails to satisfy the Rule 702 standards.

I. DR. PLUNKETT'S SCIENCE-BASED OPINIONS SHOULD BE EXCLUDED.

Dr. Plunkett purports to offer a variety of science-based opinions, including that valsartan drug products contained "NMDA and NDEA impurities" that rendered them "less safe" and that the presence of these alleged nitrosamine impurities resulted in "an increased cancer risk." (Plunkett Rep. at 4.) Dr. Plunkett's science-based opinions are inadmissible because: (1) she is not qualified to offer them; (2) she merely parrots other experts; and (3) "any exposure" opinions like hers have been widely rejected.

A. Dr. Plunkett Is Not Qualified To Provide Science-Based Opinions.

Under Rule 702, an expert must be qualified "by knowledge, skill, experience, training, or education." Fed. R. Evid. 702. Although the standard for expert qualifications is a liberal one, an expert must still have some sort of qualifications in the specific subject matter. *See Yazujian v. PetSmart*, 729 F. App'x 213, 215-16 (3d Cir. 2018) (excluding expert who "had no academic background in retail safety, no formal training in retail management or safety, and no retail work experience other than a job as a stock clerk more than 50 years

prior"); *Gayton v. McCoy*, 593 F.3d 610, 617 (7th Cir. 2010) (the proper "question" for a court to "ask is not whether an expert witness is qualified in general, but whether her 'qualifications provide a foundation for [her] to answer a specific question'") (citation omitted). Importantly, "[i]f an expert's area of experience 'is adjacent to, but not actually encompassing, the subject matter of his testimony, he may be deemed unqualified.'" *D & D Assocs., Inc. v. Bd. of Educ. of N. Plainfield*, No. Civ.A. 03-1026(MLC), 2006 WL 755984, at *3 (D.N.J. Mar. 20, 2006) (citation omitted). Dr. Plunkett's science-based opinions clearly exceed her areas of expertise and should therefore be excluded.

First, although Dr. Plunkett states in her report that she "was asked to provide opinions related to the human health risks associated with the presence of contaminants and impurities in a drug such as valsartan that is taken on a repeated basis by patients to treat chronic health conditions" (Plunkett Rep. at 7), she is not qualified to provide an opinion regarding alleged "human health risks." For one, she is ***not*** a medical doctor – Dr. Plunkett holds degrees in zoology and pharmacology. (*See* CV of Laura M. Plunkett, Ph.D. ("Plunkett CV") at 1 (App. A to Plunkett Rep.).) In fact, Dr. Plunkett testified that when confronted by friends and family about whether there is an "increased risk of cancer" associated with the use of valsartan, her advice was "[t]alk to your doctor." (Dep. of Laura M. Plunkett ("1/12/23 Plunkett Dep.") 35:10-36:2, Jan. 12, 2023 (Ex. 2 to Davidson

Cert.).) Moreover, although Dr. Plunkett purports to opine that any level of nitrosamine exposure increases the risk of cancer (which is a patently unreliable and unscientific theory, as discussed *infra*), she conceded at her deposition that she does not have the requisite credentials to offer such an opinion because she is "not a causation expert as it relates to injuries." (*Id.* 11:1-4, 15-24, 64:24-65:9.)

Second, Dr. Plunkett should also be precluded from offering chemistry-based opinions at trial. (*See, e.g.*, Plunkett Rep. ¶ 41 (describing the "chemical structures of NDMA and NDEA"); 1/12/23 Plunkett Dep. 177:20-178:22 ("Q: If you offer the opinion that it has been known that DMF can decompose in certain circumstances, right, is that one of your opinions? A: It's . . . my opinion that . . . if they had done a chemical risk assessment, they would have been able to understand the potential for formation of genotoxic impurities like the nitrosamines.").) Dr. Plunkett does not hold a degree or have any practical experience in organic chemistry. (*See* Plunkett CV; 1/12/23 Plunkett Dep. 86:1-3 ("Q. Do you have a degree in organic chemistry? A. No . . . .").) Dr. Plunkett also disclaimed any expertise in organic chemistry at her deposition. (*See, e.g.*, 1/12/23 Plunkett Dep. 176:23-177:12 ("I'm not the chemist . . . ."); *id.* 139:7-18 ("Q: Are you offering an opinion in this case as to the conditions that are necessary for DMF to degrade? A: No. I believe that's what the chemist is doing."); *id.* 46:8-24 ("Dr. Hecht and the chemists in the case are the ones to talk to if you want to understand

the chemistry . . . .").) As such, Dr. Plunkett's chemistry-based opinions are plainly beyond the scope of her expertise. *See Castaic Lake Water Agency v. Whittaker Corp.*, No. 00-12613 AHM (Rzx), 2002 WL 34700741, at *5 (C.D. Cal. Oct. 25, 2002) (finding an opinion unreliable because the expert sought to "offer the opinion of a chemist as his own expert opinion in a field for which he is not qualified" given that "[c]hemistry is simply not [the expert's] field").

For these reasons alone, Dr. Plunkett's science-based opinions should be excluded.

B. Dr. Plunkett's Chemistry-Based Opinions Are Inadmissible Because She Impermissibly Parrots Dr. Hecht.

Presumably due to her lack of scientific expertise and qualifications, Dr. Plunkett's chemistry-based opinions add nothing unique to this case, but rather impermissibly parrot opinions proffered by plaintiffs' expert Dr. Hecht. For this reason, too, Dr. Plunkett's science-based opinions should be excluded in their entirety.

Although an expert may rely upon another expert's opinion in formulating her own views, an "[e]xpert[] may not simply 'parrot' the ideas of other experts and should not 'become the mouthpiece of the witness on whose statements the expert purports to base his opinion.'" *Torain v. City of Philadelphia*, No. 14-1643, 2023 WL 174952, at *5 (E.D. Pa. Jan. 12, 2023) (citation omitted); *see also Dura Auto. Sys. of Ind., Inc. v. CTS Corp.*, 285 F.3d 609, 612-14 (7th Cir. 2002) (stating that an

expert "is not permitted to be the mouthpiece of a scientist in a different specialty"). This is so because Federal Rule of Evidence 703 "contemplates that a testifying expert can 'validate the facts, data and opinions he relied upon . . . and be subject to cross-examination on them.'" *Muhsin v. Pac. Cycle, Inc.*, No. 2010-060, 2012 WL 2062396, at *4, *8 (D.V.I. June 8, 2012) (citation omitted). Indeed, "experts who use data in their reports without independently verifying the accuracy or reliability of those figures fail to satisfy th[e] [Third] Circuit's reliability requirement." *Bruno v. Bozzuto's, Inc.*, 311 F.R.D. 124, 138 (M.D. Pa. 2015); *see also In re TMI*, 193 F.3d at 716 (affirming exclusion of expert where the expert's "failure to assess the validity of the opinions of the experts he relied upon together with his unblinking reliance on those experts' opinions, demonstrates that the methodology he used to formulate his opinion was flawed under *Daubert* as it was not calculated to produce reliable results"); *see also Quiles v. Bradford-White Corp.*, No. 10-CV-747, 2012 WL 1355262, at *7 (N.D.N.Y. Apr. 18, 2012) ("Simply stated, an expert's opinion must be based upon his own application of principles within his expertise to the facts of the case. An expert cannot simply parrot the findings of another arrived at in another context.").

Dr. Plunkett's report impermissibly serves as the "mouthpiece" for the science-based opinions of another plaintiffs' expert, Dr. Hecht. Indeed, Dr. Plunkett's reliance on Dr. Hecht and "chemists" for her science-based opinions is

widespread – she referenced Dr. Hecht and "chemists" ***more than 30 times*** at her deposition.

Dr. Plunkett seeks to opine, for example, that "evidence in this case shows that Defendants could or should have had some knowledge about the risk of N-nitroso compound formation and the presence of the general class of nitrosamine impurities in valsartan." (Plunkett Rep. at 30.) But when pressed on the basis for this opinion (i.e., how ZHP's manufacturing processes supposedly resulted in the formation of NDMA and NDEA), Dr. Plunkett repeatedly "refer[red] [counsel] to Dr. Hecht" and the "other experts, chemists in the litigation." (1/12/23 Plunkett Dep. 26:22-27:11 ("Q. Can NDEA be formed with tertiary amines, or amines? . . . [A.] I'll refer you to Dr. Hecht or all the other experts, chemists in the litigation to describe those kinds of details."); *id.* 46:8-24 ("Dr. Hecht and the chemists in the case are the ones to talk to if you want to understand the chemistry and what was so important about this step or that step."); *id.* 76:10-15 ("Q: Do you know why NDMA's properties make it difficult to find? A. The same answer. It's my understanding others can answer these questions for you as chemists, and I'm not the chemist in the case so I would defer to Dr. Hecht.").) And Dr. Plunkett made clear that her opinion about "foreseeability" – i.e., whether ZHP "should have known" that impurities could form – was "beyond the scope of [her] work" and "is what the chemist has done in this particular case." (*Id.* 81:17-21 ("It's beyond the

scope of my work from the aspect of the chemistry of the reactions or the description of the foreseeability based upon an analysis of chemical process, which is what the chemist has done in this particular case."); *id.* 229:18-231:8 ("Dr. Hecht, the chemist, has many pages in his report where he discusses the -- these issues about the chemical reactions and the foreseeability.").)

Although Dr. Plunkett points to a book and an article in support of her opinion about what was known in the scientific community, it is the exact same book and article cited by plaintiffs' chemistry experts, and Dr. Plunkett admits that she had no knowledge of either source until they were provided to her by plaintiffs' counsel after she became involved in this litigation. (1/12/23 Plunkett Dep. 28:12-14 ("Q. Have you seen the Australian textbook before serving as a[n] expert in this litigation? A. That was not one I had in my files, no."); *id.* 179:2-12 ("Q. For that opinion you cite an Australian textbook which you found in prior depositions in this litigation, correct? A. . . . that is correct. Q. Have you ever seen that Australian textbook before this litigation? A. You already asked me that and I said I had not, I said I had not seen that textbook, it's not one that I have in my library."); *id.* 30:14-31:23 (Dr. Plunkett admitting that her opinion that it was "widely known" in 2012 that DMF could degrade into diethylamine was based on "documents that [she] obtained through this litigation").)

Similarly, when asked to substantiate her opinion that ZHP conducted an "inadequate risk assessment" (*see, e.g.*, Plunkett Rep. ¶ 27), Dr. Plunkett wholly deferred to Dr. Hecht "to talk about the details of the [risk assessment] process and what it was that, from the chemist's point of view, was so critical." (1/12/23 Plunkett Dep. 45:6-23; *see also id.* 177:20-178:8 ("It's . . . my opinion that it was known before this product was -- you had this issue with this product, but if they had done a chemical risk assessment, they would have been able to understand the potential for formation of genotoxic impurities like the nitrosamines. I, however, did not attempt to do an analysis or root cause analysis or even a full chemical analysis of their processes. Again, that was what the chemist has done in this case. That was beyond my scope.").) Indeed, Dr. Plunkett was unable to provide ***any*** independent opinions regarding what specific steps ZHP should have undertaken with respect to its risk assessment. (*See id.* 45:6-18 ("Q. What specific things should ZHP have done in its risk assessment that it didn't do, like what specific tasks? . . . A. I don't think I could -- I don't think I have laid out a set of specific tasks in my report . . . .").)

To the extent Dr. Plunkett offers any basis beyond mere parroting for her risk assessment opinion, her reasoning is completely circular and therefore unreliable. With no independent knowledge or expertise regarding risk assessments for pharmaceutical API, Dr. Plunkett essentially opines that the risk

assessment was inadequate because it did not find nitrosamines. (*See, e.g.*, 1/12/23 Plunkett Dep. 44:19-45:2 ("[I]f the company had done the proper risk assessment, chemical process assessment at the time that they changed from the TIN process to the other process they were using, I believe, it's my opinion that the risk assessment would have led to, potentially, some knowledge about this issue . . . .").) But such "circular reasoning fails to reveal a sufficiently rigorous analytical connection between [Plunkett's] methodology and h[er] opinion." *Bocoum v. Daimler Trucks N. Am. LLC*, No. 17 Civ. 7636 (JPC) (BCM), 2022 WL 902465, at *11 (S.D.N.Y. Mar. 28, 2022) (citation omitted) (excluding opinion that a certain part in a vehicle must have been structurally compromised prior to a crash where the only basis for the expert's assertion was the fact that the part was discovered fractured following the crash); *see also, e.g.*, *Daniels v. Grand Lux Cafe, LLC*, No. 12-7848 (JEI/KMW), 2015 WL 1398325, at *7 (D.N.J. Mar. 26, 2015) (excluding opinion regarding adequacy of corporate policies because it rested on circular logic – that the policies were inadequate because the policies were violated, which was "not a sound foundation"); *In re Zoloft (Sertraline Hydrochloride) Prods. Liab. Litig.*, MDL No. 2342, 2015 U.S. Dist. LEXIS 161355, at *57 (E.D. Pa. Dec. 2, 2015) ("It is improper for an expert to take a results-driven approach to a question, molding his methodology and selectively

relying upon data so as to confirm his preconceived opinion."), *aff'd*, 858 F.3d 787 (3d Cir. 2017).

In short, Dr. Plunkett's chemistry-based opinions are based primarily on an "unblinking reliance" on Dr. Hecht and are otherwise conclusory and circular. *In re TMI*, 193 F.3d at 716. For this reason, too, they should be excluded from trial.

C. Dr. Plunkett's "Any Exposure" Opinion Is Contrary To Basic Toxicology Principles.

Dr. Plunkett also holds the opinion that the presence of ***any*** nitrosamine impurities in valsartan increases the risk of cancer. (*See, e.g.*, 1/12/23 Plunkett Dep. 113:25-114:10 ("Q. Would any exposure to NDMA through Valsartan increase the risk of cancer? . . . [A.] I believe that in this case, based upon what I know is occurring, that your risk is increased with your exposure to the impurities in Valsartan. It increases your risk because of the issue that there is no threshold or safe dose that's been identified for a cancer-causing ingredient."); *id.* 15:11-16:22 ("[T]he presence of this ingredient in Valsartan, where there is no known safe dose generally of these impurities . . . generally the statement is that it increases the risk of cancer."); *id.* 112:15-24 ("There is no safe dose of NDMA that's been defined.").)

Courts across the country have rejected such "any exposure" approaches as unreliable. *See, e.g.*, *McClain v. Metabolife Int'l, Inc.*, 401 F.3d 1233, 1241-42 (11th Cir. 2005) (opinion that "any level [of exposure] is too much" is unreliable

under *Daubert* and Rule 702 because it "conflicts with the importance of individual responses to toxins"); *Krik v. Exxon Mobil Corp.*, 870 F.3d 669, 677 (7th Cir. 2017) ("[M]ore than thirty other federal courts and state courts have held that this cumulative/'any exposure' theory is not reliable."); *Anderson v. Ford Motor Co.*, 950 F. Supp. 2d 1217, 1224 (D. Utah 2013) (concluding that the "every exposure" counts theory, as presented by the plaintiff's experts, "is based on their lack of information sufficient to show the level of exposure which does not create a risk of mesothelioma"; "This is not reliable enough evidence for the [c]ourt to allow it in under the standards of *Daubert* and Rule 702."). As these courts have explained, such a theory "ignore[s] fundamental principles of toxicology that illnesses like cancer are dose dependent" – i.e., "the risk" of developing the disease "depends on the length of time of exposure and the amount of exposure." *Krik*, 870 F.3d at 674-75; *see also McClain*, 401 F.3d. at 1241-42 ("The expert who avoids or neglects this principle of toxic torts without justification casts suspicion on the reliability of his methodology.").

Accordingly, Dr. Plunkett's opinion that "any exposure" to nitrosamines can contribute to cancer must be excluded as unsupported.

II. DR. PLUNKETT'S LEGAL AND REGULATORY OPINIONS SHOULD BE EXCLUDED.

Dr. Plunkett also seeks to offer a number of legal and regulatory opinions at trial, including opinions about "the regulations and industry standards that apply with

respect to manufacturing of human drug products" (Plunkett Rep. at 7) and opinions that: (1) valsartan was not "the generic equivalent of the FDA-approved branded drug" due to the presence of impurities (*id.* at 4); (2) "drug manufacturers have an ongoing duty throughout the lifecycle of a drug product that includes the duty to perform adequate risk assessments and to develop and use suitable methods to detect impurities" (*id.*; *see also id.* ¶ 30 ("drug manufacturers have a duty to ensure that the impurity profiles of generic drug products, even after initial approval, do not change over time")); and (3) "[t]he lack of conformity with applicable cGMPs and the presence of nitrosamines in valsartan API and finished drug products rendered valsartan drug products adulterated as defined in FDA laws and regulations" (*id.* at 5). Dr. Plunkett is not qualified to offer these opinions, and they are separately inadmissible because they are not reliable.

A. Dr. Plunkett Is Not Qualified To Provide Legal Or Regulatory Opinions.

As an initial matter, Dr. Plunkett should be precluded from offering legal or regulatory opinions because she does not have any legal or regulatory training. *See, e.g.*, *Kaufman v. Pfizer Pharms., Inc.*, No. 1:02-CV-22692, 2011 WL 7659333, at *6-7 (S.D. Fla. Aug. 4, 2011) (precluding expert from testifying that defendants "breached the standard of care of a 'responsible drug manufacturer'" where expert had failed to show how her regulatory or other professional experience "provided sufficient basis for her to render such an opinion"); *Tindall v.*

H & S Homes, LLC, No. 5:10-CV-044(CAR), 2012 WL 3242128, at *5-6 (M.D. Ga. Aug. 7, 2012) (expert was not qualified to "offer an opinion about Georgia law" where he was "not a lawyer and has no prior experience as an expert on the issues of corporate separateness, alter ego, or piercing the corporate veil"); *Reeves v. Commonwealth Edison Co.*, No. 06 C 5540, 2008 WL 239030, at *7 (N.D. Ill. Jan. 28, 2008) (finding expert unqualified to opine that statute required plaintiffs to make certain disclosures because he was "not a lawyer and does not have any legal training"). Indeed, although Dr. Plunkett describes her "training and experience in . . . FDA regulation of human drugs" as a basis for her regulatory opinions (Plunkett Rep. ¶¶ 7, 13), Dr. Plunkett has never been an employee of the FDA (*see* 1/12/23 Plunkett Dep. 19:14-16), has never been a consultant for the FDA (*id.* 19:17-23), has never been invited by the FDA to speak on a panel (*id.* 262:16-22) and has never been asked by the FDA for her views on nitrosamines (*id.* 248:18-24). Several courts have barred Dr. Plunkett from opining about FDA regulatory matters for similar reasons. *See, e.g.*, *Coordination Proceeding Special Title (Rule 1550(b))*, No. 4247, 2006 WL 6122225 (Cal. Super. Ct. Aug. 1, 2006) (trial order); *In re Tex. Second Region Baycol Litig.*, No. 0247408 et al., 2004 WL 5644643 (Tex. Dist. Ct. Jan. 26, 2004) (trial order); *see also* Tentative Ruling Permitting Dr. Plunkett's Ops. in Part ("*Echeverria* Ruling"), *Lloyd v. Johnson & Johnson (Pl. Eva Echeverria only)*, No. BC628228 (JCCP No. 4872) (Cal. Super. Ct.) (Ex. 3 to

Davidson Cert.) (precluding Dr. Plunkett from testifying that compliance with FDA regulations required Johnson & Johnson to warn of the risks of talc-based powders).

This Court should do the same. Dr. Plunkett seeks to tell the jury about ZHP's legal and regulatory "dut[ies]" (*see e.g.*, Plunkett Rep. ¶ 30; 1/12/23 Plunkett Dep. 133:24-134:9 (Dr. Plunkett testifying that "manufacturers have a duty to ensure at all times during the life cycle of their product that it's safe and effective for the use as indicated. As a result, the manufacturers have a duty to do what they need to do to make sure that's the case.")), a pure legal opinion that Dr. Plunkett is unqualified to offer. She also dedicates a large swath of her report to summarizing and opining on FDA regulations. (*See, e.g.*, Plunkett Rep. at 5 (opining that "valsartan drug products [are] adulterated as defined in FDA laws and regulations"); *id.* at 7-26 (dedicating a section of her report to discussing "[r]egulation of human drugs in the U.S."); *id.* ¶ 62 ("the lack of conformity with cGMPs and the presence of nitrosamines in valsartan API and finished drug products rendered valsartan drug products adulterated as defined in FDA laws and regulations").) And Dr. Plunkett also seeks to opine about ZHP's alleged "lack of conformity with applicable cGMPs" (Plunkett Rep. at 5), even though she has no relevant credentials to so opine – which is presumably why she did not even attempt to perform a cGMP compliance analysis. (1/12/23 Plunkett Dep. 185:23-

25 (testifying that she "wasn't doing a [c]GMP compliance analysis, in the way other experts were doing").) These opinions plainly fall outside of Dr. Plunkett's expertise.

B. Dr. Plunkett's Regulatory Opinions Are Also Inadmissible To The Extent They Merely Parrot Dr. Bain.

Dr. Plunkett's regulatory opinions are also inadmissible to the extent she is simply relying on the opinions of plaintiffs' expert Susan Bain (who is herself unqualified to opine on cGMP and regulatory matters). *In re TMI*, 193 F.3d at 716 (affirming exclusion of expert where the expert's "failure to assess the validity of the opinions of the experts he relied upon together with his unblinking reliance on those experts' opinions, demonstrates that the methodology he used to formulate his opinion was flawed under *Daubert* as it was not calculated to produce reliable results").

For example, Dr. Plunkett seeks to opine that ZHP's "lack of conformity with applicable cGMPs and the presence of nitrosamines . . . rendered valsartan drug products adulterated as defined in FDA laws and regulations." (Plunkett Rep. at 5.) But as previously discussed, Dr. Plunkett also testified that she "wasn't doing a GMP compliance analysis, in the way other experts were doing" (1/12/23 Plunkett Dep. 185:23-25), and that "Dr. Bain is the one, and others, that are doing GMP compliance" (*id.* 148:16-17; *see also id.* 146:24-147:4 (Dr. Plunkett explaining that she doesn't opine that "'They violated this regulation,' or, 'They

violated that regulation' Because that analysis was being done by, in my -- the information was given in the reports I've seen by other experts.")). Because Dr. Plunkett simply defers to Dr. Bain on many regulatory issues, particularly those related to cGMPs, and did not do any work to independently analyze or verify those opinions, they should be excluded from trial for this reason as well.

C. Dr. Plunkett's Regulatory Opinions Are Inadmissible.

Finally, Dr. Plunkett's opinions about the relevant regulatory requirements and defendants' compliance with the governing legal and regulatory frameworks should also be excluded because they would impermissibly usurp the role of the Court and the jury.

First, Dr. Plunkett's legal opinions regarding bioequivalence and, by extension, her opinion that ZHP's products were adulterated because they purportedly lacked bioequivalence (*see* Plunkett Rep. at 4-5), would impermissibly usurp the role of the Court and the jury, as this Court has already held with respect to another plaintiffs' expert. (*See* Class Certification Ruling at 91 (excluding expert Dr. Najafi's opinions "about what is bioequivalence" because it "wades too far into the factfinder's domain").)

"[E]xperts generally may not testify to what the law *requires* or whether a party *complied* with the law . . . ." *Moorestown Twp. Bd. of Educ. v. S.D.*, No. 10-0312 (RMB), 2010 WL 4062182, at *5 (D.N.J. Oct. 15, 2010). Consistent with

this principle, courts have refused to allow experts to offer opinions on a pharmaceutical company's compliance with applicable regulations. *See, e.g.*, *Stanley v. Novartis Pharms. Corp.*, No. 11-03191 JGB (OPx), 2014 U.S. Dist. LEXIS 198861, at *10 (C.D. Cal. May 6, 2014) (precluding an expert from "offer[ing] legal conclusions, including whether [d]efendant was in regulatory compliance with the FDA"); *In re Tylenol (Acetaminophen) Mktg., Sales Pracs., & Prods. Liab. Litig.*, MDL No. 2436, 2016 U.S. Dist. LEXIS 98858, at *8-9 (E.D. Pa. July 27, 2016) (excluding expert opinion regarding whether a drug met a certain standard pursuant to FDA regulations, as such an opinion "would require a legal interpretation" of that standard); *In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 557 (S.D.N.Y. 2004) (holding that opinions regarding "the duties of pharmaceutical companies are not appropriate expert testimony because they embrace ultimate questions of law outside the province of an expert"). Indeed, in its Class Certification Ruling, this Court excluded Dr. Najafi's Class Certification Report on the basis that "the subject matter of Dr. Najafi's opinions [in his Class Certification Report], about what is bioequivalence, wades too far into the factfinder's domain." (Class Certification Ruling at 91.)

Dr. Plunkett seeks to opine on whether ZHP complied with FDA regulations on bioequivalence (Plunkett Rep. at 4 (Dr. Plunkett opining that valsartan was not "the generic equivalent of the FDA-approved branded drug" due to the presence of

impurities)) and adulteration based on "[t]he lack of conformity with applicable cGMPs" (*id.* at 5 (Dr. Plunkett opining that valsartan was "adulterated as defined in FDA laws and regulations" due to "[t]he lack of conformity with applicable cGMPs")). But, as this Court has already recognized, these opinions improperly invade the role of the factfinder and should be excluded.

Dr. Plunkett's opinions regarding what the FDA "requires" and the meaning of specific statutory terminology is also inadmissible. "[I]t is well-settled that matters of statutory construction are not a proper subject for expert testimony, but rather, questions of law to be resolved by the [c]ourt." *Moorestown Twp. Bd. of Educ.*, 2010 WL 4062182, at *5 (citing authority). Notably, Dr. Plunkett has previously been precluded from testifying about "what reporting requirements [d]efendants had under FDA regulations and whether [d]efendants met them," noting that much of her testimony "consist[ed] of quoted portions of the [FDA] regulations themselves or descriptions of what the regulations require" and created a risk that jurors would "mistakenly conclude that her opinion or conclusion is the law." *Newman ex rel. Newman v. McNeil Consumer Healthcare*, No. 10 C 1541, 2013 WL 9936293, at *5 (N.D. Ill. Mar. 29, 2013); *see also Echeverria* Ruling at 5.

Here again, as in *Newman*, Dr. Plunkett merely quotes from certain FDA regulations, interprets their meaning and then opines on the supposed legal

responsibilities and duties of API manufacturers. (*See, e.g.*, Plunkett Rep. ¶ 30 ("drug manufacturers have a duty to ensure that the impurity profiles of generic drug products, even after initial approval, do not change over time"); *id.* ¶¶ 53-60 (opining on the "responsibilities" of drug manufacturers); *id.* ¶ 60 ("evidence in this case shows that when a company fails to fulfill its duties under the FDA regulations and other industry standards, patient health is put at risk").) Because there is a significant risk that jurors will "mistakenly conclude that [Dr. Plunkett's] opinion[s] or conclusion[s] [are] the law," *Newman*, 2013 WL 9936293, at *5, these opinions are inadmissible.

III. DR. PLUNKETT SHOULD NOT BE PERMITTED TO OFFER ANY OPINIONS REGARDING THE CONDUCT OF THE FINISHED DOSE MANUFACTURERS.

A. Dr. Plunkett's Opinions About The Finished Dose Defendants Are Conclusory And Are Not Based On Any Discernible Methodology.

Dr. Plunkett also seeks to offer a number of conclusory opinions as to Teva and Torrent (collectively, "the Finished Dose Defendants"). None of these opinions should be admitted because: (1) Dr. Plunkett performed only a cursory review of a handful of documents pertaining to the Finished Dose Defendants and her "methodology" in arriving at opinions without such review is unreliable; and (2) her opinions as to whether the Finished Dose Defendants complied with applicable regulations and cGMPs suffer from the same flaws discussed in section II, above.

As Dr. Plunkett acknowledged at her deposition, she did not review a single deposition of a Teva corporate witness (1/12/23 Plunkett Dep. 296:5-297:6), and although she had access to Teva's ANDA files, she only reviewed a grand total of 18 Teva corporate documents (*id.* 297:17-298:12). With respect to Torrent, Dr. Plunkett reviewed a single deposition transcript and 24 total corporate documents. (Dep. of Laura M. Plunkett ("2/10/23 Plunkett Dep.") 383:7-16, Feb. 10, 2023 (Ex. 4 to Davidson Cert.).) She acknowledged that her review of Teva and Torrent material was limited and that she would defer to other experts who performed "much more detailed reviews" of the Finished Dose Defendants' material. (1/12/23 Plunkett Dep. 308:11-309:5.) Unfortunately, Dr. Plunkett's failure to review any relevant documentation did not prevent her from offering groundless opinions.

For example, at her deposition Dr. Plunkett purported to offer criticisms of Teva's risk assessments related to the valsartan API sourced from ZHP, but she did not review the risk assessments. (*See id.* 298:13-302:22.) She claimed that a "proper" risk assessment by any of the ANDA holders would have identified the presence of NDMA in ZHP's valsartan API, but again admitted that she did not review the risk assessments that would have enabled her to form an opinion as to whether they were "proper." (*Id.* 305:22-306:24.) Her report also contains an opinion that the Finished Dose Defendants did not take action to warn patients

about the presence of impurities in valsartan drug products on their own, but she did not review and was apparently unaware of the patient-level recall notices sent by both Teva and Torrent. (*Id.* 317:14-318:19, 321:23-322:16.) Clearly, Dr. Plunkett's opinions as to the Finished Dose Defendants are based on her assumption that because the impurity was present in valsartan drug products, "something" must have been deficient about their conduct. She did not arrive at these conclusions by reviewing the relevant materials and forming opinions based on that review – indeed. she disclaimed the need to review or even evaluate such documents. (*Id.* 307:4-14.) Such opinions arrived at without a verifiable methodology cannot be allowed to reach the jury. *See In re TMI Litig.*, 193 F.3d 613, 687 (3d Cir. 1999).

Finally, even if Dr. Plunkett had reviewed sufficient material related to the Finished Dose Defendants and had arrived at her opinions after evaluating said material rather than assuming the fault of those parties as a starting point, her regulatory opinions as to the Finished Dose Defendants suffer from the same flaws outlined in section II above, and should be excluded on those same bases.

B. Dr. Plunkett's Opinion That The Finished Dose Defendants Were Required To Obtain Access To The Closed Portion Of The Valsartan DMF Is Not Contained In Her Expert Report And Is Unsupported By Any Applicable Statute, Rule Or Regulation.

At the close of her first day of deposition testimony, Dr. Plunkett offered a new opinion not contained anywhere in her expert report, namely that the Finished

Dose Defendants "should have obtained access to ZHP's Drug Master File." (1/12/23 Plunkett Dep. 303:11-16, 323:3-17; *see generally* Plunkett Rep.) This previously undisclosed opinion should be excluded on that basis alone. Fed. R. Civ. P. 26(a)(2)(B)(i); *see Krys v. Aaron*, 112 F. Supp. 3d 181, 207 (D.N.J. 2015) (an expert may not present new opinions on topics not timely included or otherwise disclosed in the expert's report); *see also Johnson v. Vanguard Mfg., Inc.*, 34 F. App'x 858, 859 (3d Cir. 2002) (affirming exclusion of expert opinion not disclosed in report).

However, this opinion is also improper because – like the rest of Dr. Plunkett's opinions as to the Finished Dose Defendants – it is not grounded in any methodology and Dr. Plunkett could not identify any statute, rule, regulation, or other source suggesting that obtaining such access is required of finished dose manufacturers. (2/10/23 Plunkett Dep. 364:21-367:2, 372:17-373:16.) To the contrary, as she acknowledged, the very purpose of Drug Master Files as codified in 21 C.F.R. § 314.420 is to allow a finished dose manufacturer to incorporate API manufactured by another company into finished drug product ***without*** the API manufacturer having to disclose proprietary information in the closed portion of the DMF to the finished dose manufacturer. (*Id.* 369:15-370:9.) Accordingly, Dr. Plunkett should be prohibited from offering the opinion that the Finished Dose

Defendants should have obtained access to the closed portion of ZHP's valsartan DMF.

CONCLUSION

For the foregoing reasons, defendants respectfully request that the Court exclude Dr. Plunkett's testimony from trial.

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Respectfully submitted,

By: */s/ Jessica Davidson*

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on March 13, 2023, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system, which will send a notice of electronic filing to all CM/ECF participants in this matter.

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